

K111971 1/2

5. 510(k) Summary

JAN 23 2012

General Information

Date Compiled January 21, 2012

Classification Class II, 21 CFR § 888.3040 Smooth or threaded metallic bone fixation fastener
Primary Product code HWC
Class II, 21 CFR § 888.3030, Single/multiple component metallic bone fixation appliances and accessories
Secondary Product code HTN

Trade Name Synde-Lock™ Syndesmosis Repair Kit

Submitter Tarsus Medical, Inc.
465 Fairchild Drive
Suite 230
Mountain View, CA 94043

Contact Nicholas Moulas
President and CEO
Tel: (650) 237-0070
Fax: (650) 237-0071

Intended Use

The Tarsus Synde-Lock Syndesmosis Repair Kit is intended to provide fixation during the healing process following a syndesmotic trauma.

Predicate Device

TightRope Syndesmosis Device Plus K043248
Manufactured by Arthrex

Device Description

The Synde-Lock™ Syndesmosis Repair Kit contains an implant designed as two bone anchors, one a stainless steel screw and the other a PEEK T-nut, connected by a distribution bridge comprised of UHMWPE suture and a threaded PEEK rod. The stainless steel screw is pre-threaded with the UHMWPE suture section of the distribution bridge. The PEEK T-nut engages the threads of the PEEK section of the distribution bridge allowing the effective length of the bridge to be shortened. A clipper is also contained in the kit to cut away excess distribution bridge material, once the implant is in place. The Tarsus Synde-Lock Syndesmosis Repair Kit is intended to provide fixation during the healing process following a syndesmotic trauma.

Materials

The Synde-Lock™ Syndesmosis Device is comprised of 316 LVM stainless steel conforming to ASTM F138-08, Ultra High Molecular Weight Polyethylene (UHMWPE) suture conforming to USP 33, and Polyetheretherketone (PEEK) conforming to ASTM F2026-08.

Testing

The non-clinical tests performed by the company include lateral displacement testing, external rotation testing, fatigue testing with lateral tensile to failure, and external rotation to failure. Both synthetic bone analog and cadaveric bone were used for testing. The test results demonstrate that the Synde-Lock™ Syndesmosis Repair Kit is substantially equivalent to the legally marketed predicate device.

Summary of Substantial Equivalence

Tarsus Medical, Inc. believes the Synde-Lock™ Syndesmosis Repair Kit is substantially equivalent to the predicate product. The intended use, method of operation, methods of construction and materials used, are either identical or substantially equivalent to the existing legally marketed predicate product.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Tarsus Medical, Inc.
% Nicholas J. Mourlas, Ph.D.
465 Fairchild Drive, Suite 230
Mountain View, CA 94043

JAN 23 2012

Re: K111971

Trade/Device Name: Synde-Lock™ Syndesmosis Repair Kit
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, HTN
Dated: December 8, 2011
Received: December 12, 2011

Dear Dr. Mourlas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

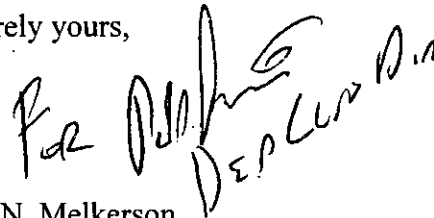
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "For Mark N. Melkerson". The signature is written in a cursive, flowing style.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

**510(k) Number
(if known):**

This application K111971

Device Name:

Synde-Lock™ Syndesmosis Repair Kit

**Indications for
Use:**

The Tarsus Synde-Lock Syndesmosis Repair Kit is intended to provide fixation during the healing process following a syndesmotic trauma.


Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111971